Remarks

Reconsideration of the above-mentioned application in view of this response is respectfully submitted.

Claim Objections

Claims 1 and 53 were objected to because of informalities. Those informalities have been corrected and thus the objection has been overcome.

Rejections under 35 U.S.C. §112

Claims 1 and 53 were rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicant has included the recitation of "adjacent" in regards to "one bone" and "the bones" to more particularly point out and distinctly claim the invention. The inclusion of "adjacent" cures the indefiniteness of the claim and thus overcomes the rejection.

Rejections under 35 U.S.C. §102

In the Office Action of May 11, 2006, claims 1, 2, 7, 17, 21, 24, 30, 33, 36, 53, and 54 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,728,116 to Rosenman (hereinafter 'Rosenman'). These rejections are respectfully traversed.

As amended, claim 1 recites an apparatus for attaching a first bone to an adjacent second bone, the second bone being separated from the first bone by a space between the adjacent bones. The apparatus comprises an anchor having a platform for drivingly rotating the anchor and at least two helical spikes for embedding into at least one of the first and second bones upon rotation of the platform. The platform has a first surface that is solid and that extends generally transverse to a longitudinal axis of the anchor. The at least two helical

spikes project tangentially from the first surface of said platform and extend around the longitudinal axis.

Rosenman appears to teach a surgical tack 10 having a distally extending spiral member 50 extending down from the bottom surface 40 of the base member 30. The distally extending member 50 preferably is shaped to form a spiral 60 having coils 65 of constant size 65, although the size of the coils may vary along the longitudinal length of the spiral (Col. 3, lines 59-66). The spiral 50 consists of at least one coil 65 (Col. 2, lines 28-29). Therefore, Rosenman does not teach at least two helical spikes projecting tangentially from a first surface of the platform, as recited in amended claim 1. As the Examiner notes, Rosenman displays only one helical spike (Office Action, pg. 3). However, the fact that the spiral consists of at least one coil (Col. 2, lines 28-29) does not mean that Rosenman teaches at least two helical spikes, as recited in amended claim 1; it means that there is at least one turn (coil) on that single spike. Therefore, Rosenman does not teach at least two helical spikes projecting from the platform. Furthermore, Rosenman appears to teach that the mechanical characteristics of the materials of construction, e.g., stiffness, will be sufficient to effectively enable the tack 10 to penetrate tissue without deforming (Col. 6, lines 17-20). However, the 'tissue' Rosenman refers to range from soft muscle, fascia, or fat to hard ligaments and tendons (Col. 6, lines 6-8), not hard surfaces like bone. Thus, Rosenman does not teach or suggest a tip portion of the helical spike which is driven into bone as the platform is rotated. Additionally, the fact that the spike 50 of Rosenman terminates prior to the head 1 of the tack 10 renders the tacks mechanically insufficient for placement into hard surfaces (i.e. bone). Conversely, the helical spikes 50 and 52 of the present invention project from the end surface 38 of the platform 40 and ensure structural integrity during implantation into hard

surfaces. Since Rosenman does not fully anticipate the subject matter of amended claim 1, it is respectfully submitted that as amended, claim 1 patentably defines over Rosenman, and therefore is allowable.

Claims 2, 7, and 17 depend from claim 1 and are allowable for at least the same reasons claim 1 is allowable, and for the specific limitations recited in each claim.

Claim 21 recites an apparatus for attaching a fifth lumbar (L5) vertebrae to a sacrum, the apparatus comprising an anchor for extending between the L5 vertebrae and the sacrum and for attaching the L5 vertebrae to the sacrum. The anchor has a platform for drivingly rotating the anchor. The platform includes a first surface that is solid and that extends generally transverse to a longitudinal axis of the anchor. The anchor further has at least two helical spikes for embedding into both of the L5 vertebrae and the sacrum upon rotation of the platform, the at least two helical spikes projecting tangentially from the first surface of the platform and extending around the longitudinal axis. The at least two helical spikes have a tip portion at a distal end for penetrating into at least one of the L5 vertebrae and the sacrum as the platform is rotated. The anchor has a first condition in which the at least two helical spikes are embeddable into one of the L5 vertebrae and the sacrum. The anchor further has a second condition in which the at least two helical spikes are embeddable into both of the L5 vertebrae and the sacrum to attach the L5 vertebrae and the sacrum to one another while maintaining an intervertebral space between the L5 vertebrae and the sacrum. The anchor is movable from the first condition to the second condition by rotation of the platform. A portion of each of the at least two helical spikes of the anchor, when the anchor is embedded into the L5 vertebrae and the sacrum, extends across the intervertebral space between the L5 vertebrae and the sacrum.

Rosenman appears to teach a surgical tack 10 having a distally extending spiral member 50 extending down from the bottom surface 40 of the base member 30. The distally extending member 50 preferably is shaped to form a spiral 60 having coils 65 of constant size 65, although the size of the coils may vary along the longitudinal length of the spiral (Col. 3, lines 59-66). The spiral 50 consists of at least one coil 65 (Col. 2, lines 28-29). Therefore, Rosenman does not teach at least two helical spikes projecting tangentially from a first surface of the platform, as recited in claim 21. As the Examiner notes, Rosenman displays only one helical spike (Office Action, pg. 3). However, the fact that the spiral consists of at least one coil (Col. 2, lines 28-29) does not mean that Rosenman teaches at least two helical spikes, as recited in claim 21; it means that there is at least one turn (coil) on that single spike. Therefore, Rosenman does not teach at least two helical spikes projecting from the platform. Furthermore, Rosenman appears to teach that the mechanical characteristics of the materials of construction, e.g., stiffness, will be sufficient to effectively enable the tack 10 to penetrate tissue without deforming (Col. 6, lines 17-20). However, the 'tissue' Rosenman refers to range from soft muscle, fascia, or fat to hard ligaments and tendons (Col. 6, lines 6-8), not hard surfaces like bone. Thus, Rosenman does not teach or suggest a tip portion of the helical spike which is driven into bone as the platform is rotated. Additionally, the fact that the spike 50 of Rosenman terminates prior to the head 1 of the tack 10 renders the tacks mechanically insufficient for placement into hard surfaces (i.e. bone). Thus, it would not be inherent for Rosenman's invention to be used to hold the vertebrae and sacrum together, as those are hard, bony surfaces. Conversely, the helical spikes 50 and 52 of the present invention project from the end surface 38 of the platform 40 and ensure structural integrity during implantation into hard surfaces. Since Rosenman does not fully anticipate

the subject matter of claim 21, it is respectfully submitted that claim 21 patentably defines over Rosenman, and therefore is allowable.

Claims 30, 33, and 36 depend from claim 21 and are allowable for at least the same reasons claim 21 is allowable, and for the specific limitations recited in each claim.

Claim 24 recites that when the anchor is in the second condition, at least a portion of the platform is recessed into an anterior surface of the sacrum. Rosenman does not teach or suggest that a portion of the base member 20 is recessed into any of the 'soft' tissues mentioned above. The surgical tack 10 of Rosenman is designed to approximate tissues, to hold a medical device to the surface of tissue including, for example, a surgical mesh, or to anchor tissue to an anatomic site (Col. 5, lines 41-44). Since the base member 20 has a larger footprint then the distally extending member 50 (Figs. 3 and 12-15), no amount of rotation of the tack 10 into the soft tissue will result in the base member 20 being recessed into the anterior surface of the soft tissue. Furthermore, soft tissue cannot be pre-conditioned like hard tissue can to receive the head of the tack (i.e. drilled or countersunk). Since Rosenman does not teach or suggest that when the anchor is in the second condition, at least a portion of the platform is recessed into an anterior surface of the sacrum, as recited in claim 24, it is respectfully submitted that claim 24 patentably defines over Rosenman, and therefore is allowable.

As amended, claim 53 recites an apparatus for attaching a first bone to an adjacent second bone. The second bone is separated from the first bone by a space between the adjacent bones. The apparatus comprises an anchor having a platform for drivingly rotating the anchor and at least two helical spikes for embedding into at least one of the first and second bones. Upon rotation of the platform, the platform has a first surface that extends

generally transverse to a longitudinal axis of the anchor. At least two helical spikes project from the first surface of the platform and extend around the longitudinal axis. The at least two helical spikes have a tip portion at a distal end which penetrates into bone as the platform is rotated. The anchor has a first condition in which a first portion of each of the at least two helical spikes is extendable into one of the first and second bones. The anchor further having a second condition in which the first portions are extendable into the other of the first and second bones and a second portion of each of said at least two helical spikes is extendable into the one bone to attach the first and second bones to one another while maintaining the space between the bones. Each of the at least two helical spikes further includes a third portion extending between the first and second portions and that, when the anchor is embedded into the first and second bones, extends across the space between the bones, wherein one of the first and second bones is the sacrum and the other of said first and second bones is the fifth lumbar (L5) vertebrae.

Rosenman appears to teach a surgical tack 10 having a distally extending spiral member 50 extending down from the bottom surface 40 of the base member 30. The distally extending member 50 preferably is shaped to for a spiral 60 having coils 65 of constant size 65, although the size of the coils may vary along the longitudinal length of the spiral (Col. 3, lines 59-66). The spiral 50 consists of at least one coil 65 (Col. 2, lines 28-29). Therefore, Rosenman does not teach at least two helical spikes projecting tangentially from a first surface of the platform, as recited in amended claim 53. As the Examiner notes, Rosenman displays only one helical spike (Office Action, pg. 3). However, the fact that the spiral consists of at least one coil (Col. 2, lines 28-29) does not mean that Rosenman teaches at least two helical spikes, as recited in amended claim 53; it means that there is at least one

turn (coil) on that single spike. Therefore, Rosenman does not teach at least two helical spikes projecting from the platform. Furthermore, Rosenman appears to teach that the mechanical characteristics of the materials of construction, e.g., stiffness, will be sufficient to effectively enable the tack 10 to penetrate tissue without deforming (Col. 6, lines 17-20). However, the 'tissue' Rosenman refers to range from soft muscle, fascia, or fat to hard ligaments and tendons (Col. 6, lines 6-8), not hard surfaces like bone. Thus, Rosenman does not teach or suggest a tip portion of the helical spike which is driven into bone as the platform is rotated. Additionally, the fact that the spike 50 of Rosenman terminates prior to the head 1 of the tack 10 renders the tacks mechanically insufficient for placement into hard surfaces (i.e. bone). Thus, it would not be inherent for Rosenman's invention to be used to hold the vertebrae and sacrum together, as those are hard, bony surfaces. Conversely, the helical spikes 50 and 52 of the present invention project from the end surface 38 of the platform 40 and ensure structural integrity during implantation into hard surfaces. Since Rosenman does not fully anticipate the subject matter of amended claim 53, it is respectfully submitted that as amended, claim 53 is allowable.

Claim 54 recites that when the anchor is in the second condition, at least a portion of the platform is recessed into an outer surface of one of the sacrum or the L5 vertebrae. Rosenman does not teach or suggest that a portion of the base member 20 is recessed into any of the 'soft' tissues mentioned above. The surgical tack 10 of Rosenman is designed to approximate tissues, to hold a medical device to the surface of tissue including, for example, a surgical mesh, or to anchor tissue to an anatomic site (Col. 5, lines 41-44). Since the base member 20 has a larger footprint then the distally extending member 50 (Figs. 3 and 12-15), no amount of rotation of the tack 10 into the soft tissue will result in the base member 20

being recessed into the anterior surface of the soft tissue. Furthermore, soft tissue cannot be pre-conditioned like hard tissue can to receive the head of the tack (i.e. drilled or countersunk). Since Rosenman does not fully anticipate the subject matter of claim 54, it is respectfully submitted that claim 54 patentably defines over Rosenman, and therefore is allowable.

Rejections under 35 U.S.C. §103

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenman in view of U.S. Patent No. 4,204,541 to Kapitanov (hereinafter 'Kapitoniv'). This rejection is respectfully traversed.

Claim 6 recites a sleeve through which the anchor is insertable, the sleeve configured to prevent the helical spikes of the anchor from deforming during implantation into one of the first and second bones. The Examiner states that Kapitanov discloses a sleeve that is used to introduce a helical anchor (Office Action, pg. 4). It is assumed that the Examiner is referring to the body 1 in Kapitanov, and not the sleeve element 14. Kapitanov appears to teach a hollow tubular body 1 which houses a tubular needle 2 for applying sutures 4 to wounds (Col. 3, lines 15-19). The body 1 is held positively to a hollow cylinder 8 through a screw 7 (Col. 3, lines 32-34). A lug 13 having a rod 10 is held relative to the cylinder 8 by a stud pin 12 that rides along the screw threads 11 of the rod 10 as the lug 13 is rotated (Col. 3, lines 35-41; Fig. 1). The needle 2 is detachably mounted at the end of the rod 10 by a sleeve 14 (Fig. 1). The tubular shaped needle 2 is introduced into the wound 16 (Fig. 7) by rotating the instrument clockwise until the body 1 contacts the surface of tissue 17 such that both of the wound lips 16 are pricked. Thereupon, the rod 10 is rotated counterclockwise by lug 13, without removing the body 1 from the wound surface, until the screw 12 thrusts

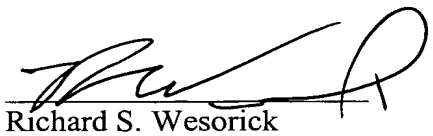
against the end of the screw thread 11 as shown in Fig. 2, such that the length of suture material 4 is left in the suture 17 to hold the wound together (Col. 4, lines 9-15; Fig. 8). Thus, the body 1 is provided to hold the device together and provide a stationary reference by which to rotate the lug 13 and therefore drive the needle 2 into the wound to apply the suture, and subsequently to rotate the lug 13 in the opposite direction to remove the needle 2. The needle 2 is applied to a wound in the skin, and therefore is not susceptible to the same bending moments that the present invention is with regards to bone implantation. There is no need to configure the tube 1 of Kapitanov to prevent the needle 2 from deforming during implantation.

Rosenman appears to teach that the mechanical characteristics of the tack 10 will be sufficient to effectively enable the tack 10 to penetrate tissue without deforming (Col. 6, lines 17-21). Therefore, there is no motivation by Rosenman to include a sleeve that prevents the tack 10 from deforming during implantation. Furthermore, the Examiner notes in the Office Action that Rosenman does not disclose the use of a sleeve (Pg. 4). Since the combination of Rosenman and Kapitanov does not teach or suggest the subject matter of claim 6, it is respectfully submitted that claim 6 patentably defines over Rosenman in view of Kapitanov, and therefore is allowable.

In view of the foregoing, it is respectfully submitted that the above-identified application is in condition for allowance, and allowance of the application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,



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